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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,081	12/28/2001	Colin Chong	047711-0284	1999

7590

09/24/2003

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/036,081

Applicant(s)

CHONG ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,22-24,44 and 47-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,22-24,44 and 47-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13-19, 22-24, 44 and 47-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al., 6,010,521.

As to claims 1, 53 and 54, Lee et al. discloses a catheter comprising a first (43) and second (42) materials defining a tubular structure ; wherein the second material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of a formulation in a catheter, see column 2, lines 37-61.

112

could be anything

ma;
if clarifying this language can't use Lee

att'y:
Lee's
reliability
anyhow
2 diff. material
with diff. permeability

As to claim 2, the first material is disposed outside the second material, see

Figure 5.

As to claim 3, the first material is disposed inside the second material, see Figure 5.

As to claim 4, the second material comprises a material that has a permeability index for the at least one substance that is lower than the permeability index of the outer material for the at least one substance, see column 2, lines 37-61.

As to claims 5-7, the catheter is capable of conveying CO₂, phenolic compounds, or phenol.

As to claims 8, 9, the second material comprises polytetrafluorethylene, see column 2, line 61.

As to claim 10, the second material comprises polyamide or polyetheretherketone, see column 2, lines 37-41, and column 3, lines 1-3.

As to claim 13, the first material is bio-compatible.

As to claim 14, the inner surface of the first material substantially covers an outer surface of the second material, see Figure 5.

As to claim 15, the inner surface of the first material covers only a portion of an outer surface of the second material, see Figure 5.

As to claim 16, the portion of the outer surface of the second material covered by the inner surface of the first material is located at the distal end, see Figure 5.

As to claim 17, the catheter further comprises an interior layer (63) contacting an inner surface of the second material, the interior layer comprising a substance that regulates an interaction of substances with the interior layer. The first material here is (62) and second material is (65 or 66).

As to claim 18, the substance is a hydrophilic substance, see column 5, lines 18-19.

As to claim 22, the proximal end of the catheter is capable of being connected to an implantable infusion pump.

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As to claim 23, the first material is more flexible than the second material, see column 2, lines 37-61.

As to claim 24, the first material has a lower flexural modulus than the second material, see column 2, lines 37-61.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., 6,010,521, in view of Bogert et al., 6,096,012.

Lee et al. discloses the invention substantially as claimed (see above), except for the second material being diamond coated.

Bogert et al. discloses a catheter having a tip that is coated with a diamond composition (28) in order to impart to the tip a hardness, lubricity and strength necessary to penetrate skin of a patient, see column 4, lines 38-49. It would have been obvious to provide a diamond coating as taught by Bogert et al. to provide a tip on the Lee et al. catheter that is capable of penetrating skin, as would be desirable for inserting the catheter in a patient.

Claims 44, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., 6,010,521, in view of Polaschegg, 4,966,579.

Lee et al. discloses the invention substantially as claimed (see above), except for a pump and sensing device for regulating the delivery of the formulation.

Polaschegg discloses a catheter, pump and sensor to provide fluid delivery to a patient. It would have been obvious to provide a pump and flow sensor as taught by Polaschegg with the Lee et al. catheter to provide fluid delivery to a patient.

Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., 6,010,521, in view of Polaschegg, 4,966,579, and further in view of Bogert et al., 6,096,012.

Lee et al. in view of Polaschegg discloses the invention substantially as claimed (see above), except for the second material being diamond coated.

Bogert et al. discloses a catheter having a tip that is coated with a diamond composition (28) in order to impart to the tip a hardness, lubricity and strength necessary to penetrate skin of a patient, see column 4, lines 38-49. It would have been obvious to provide a diamond coating as taught by Bogert et al. to provide a tip on the Lee et al.-in-view-of Polaschegg catheter that is capable of penetrating skin, as would be desirable for inserting the catheter in a patient.

Response to Arguments

Applicant's arguments filed July 7, 2003 have been fully considered but they are not persuasive. Applicant argues that neither Lee et al. '521, nor Bogert disclose a

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catheter having first and second materials wherein the second material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of a formulation. In response, Examiner asserts that the Lee et al. catheter has a second material (see column 2, lines 37-49) having a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of a formulation. Examiner asserts that the Lee device is capable of performing the claimed intended use since Applicant has not specified what is the "substance" and what is a "detrimental change".

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L. 
September 14, 2003


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
09/22/03